## REMARKS

In view of the foregoing amendments and the following representations, reconsideration and allowance of the above-identified application is respectfully requested.

Claims 1-12, 15, 16 and 19-23 are pending in the present application.

In the Office Action, the Examiner rejected claims 1-12 and 14-23 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which the applicant regards as the invention. Specifically, the Examiner asserts that claim 1 was indefinite and vague because it indicated that the proton pump inhibitor layer was coated but free from enteric coating.

In the Office Action, the Examiner rejected claims 1-12 and 14-23 under 35 U.S.C. § 102(e) as being anticipated by Phillips, United States Patent No. 6,645,988 (hereinafter "Phillips").

In response to these rejections, the Applicants have amended claim 1 to delete the reference to "coating" and "enteric coating". Claim 1 has also been amended to recite that the multilayered dosage form comprises (a) a proton pump inhibitor layer and (b) an antacid layer. The proton pump inhibitor layer further comprises a proton pump inhibitor granule and a pharmaceutical excipient. The proton pump inhibitor granule comprises (i) a proton pump inhibitor and (ii) a water insoluble film forming polymer, a congeable solid material or a mixture of a water insoluble film forming polymer and a congeable solid material. Claim 1 further recites that the proton pump inhibitor layer is free of acidic film forming polymer and enteric polymers.

Claims 8 and 9 have been amended to conform to the amendments to claim 1. Claim 22 and the paragraph on page 8, lines 4-11 of the specification have been amended to correct obvious typographical errors.

No new matter is added by these amendments. Support can be found on page 5, lines 19-25 and page 9, line 25 to page 10, line 31 of the specification. Additional support can be found in Examples 11 and 18 which employ ethylcellulose (a film forming water insoluble polymer) in the omeprazole (a proton pump inhibitor) granules, Examples 8, 15 and 17 which employ glycerol monostearate (a congeable solid material) in the omeprazole granules and Examples 14 and 16 which employ both ethylcellulose and glycerol monostearate in the omeprazole granules.

Applicants respectfully submit that the pending claims are patentable over the Phillips reference because the pending claims require a proton pump inhibitor granule that comprises (i) a proton pump inhibitor and (ii) a water insoluble film forming polymer, a congeable solid material or a combination of a water insoluble film forming polymer and a congeable solid material. This unique proton pump inhibitor granule is not disclosed, explicitly or inherently, in the Phillips reference.

The Examiner asserts that the Phillips reference describes a wide range of potential dosage forms on Col. 14, lines 9-16. Applicants agree that this section of the Phillips reference describes, in a very general sense, a wide range of possible dosage forms. Applicants respectfully submit that this broad general disclosure of various dosage forms does not anticipate or suggest to an individual of ordinary skill the multilayered dosage form as recited in the pending claim. More impotantly, there is no disclosure in the

Phillips reference that would lead an individual of ordinary skill to employ a water insoluble film forming polymer or a congerable solid material to prepare proton pump inhibitor granules as required by the pending claims. The only description of possible excipients for the solid dosage forms of the Phillips reference appears on Col. 14, lines 24-46. This very general discussion does not mention water insoluble film forming polymers or congeable solid materials as required by the pending claims.

Moreover, Col. 14, line 63 to Col. 15, line 3 of the Phillips reference describes the proton pump inhibitor granules that can be used in the disclosed dosage forms as follows:

> The granules used to make the tablets according to one embodiment of the present invention are made by either spray drying or pre-compacting the raw materials. Prior to being processed into granules by either process, the density of the alkali earth metal salts useful in the present invention ranges from about 0.3 g/ml to about 0.55 g/ml, preferably about 0.35 g/ml to about 0.45 g/ml, even more preferably about 0.37 g/ml to about 0.42 g/ml.

This description of "the granules" used in the Phillips dosage form fails to mention the use of a water insoluble film forming polymer and/or a congeable solid material to prepare the granules. Applicants' review of the working examples of the Phillips reference also fails to reveal any example that employs a proton pump inhibitor granule that comprise a proton pump inhibitor and a water insoluble film forming polymer, a congeable solid material or a combination of a water insoluble film forming polymer and a congeable solid material as required by the pending claims.

In view of the Phillips reference complete failure to provide any disclosure or even suggestion to employ proton pump inhibitor granules as recited in the pending claims, it is respectfully submitted that the Phillips reference does not anticipate the present.

Based upon the foregoing amendments and representations, Applicants respectfully submit that the rejection of the claims in the above-identified application have been overcome and should be withdrawn. Early and favorable action is earnestly solicited.

Respectfully submitted,

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